

**SECTION IV****510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION**

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as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

**Smith & Nephew KINSA RC Suture Anchor**

**MAY 16 2007**

Date Prepared: May 14, 2007

**A. Submitter's Name:**

Smith & Nephew, Inc., Endoscopy Division  
150 Minuteman Road  
Andover MA, 01810

**B. Company Contact**

Deana Boushell  
Regulatory Affairs Specialist  
Phone: (508) 337-4036  
FAX: (508) 261-3620

**C. Device Name**

Trade Name: KINSA RC Suture Anchor  
Common Name: Fastener, fixation, non-degradable, soft tissue  
Classification Name: Fastener, fixation, non-degradable, soft tissue

**D. Predicate Devices**

The Smith & Nephew KINSA RC Anchor is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution: The Smith & Nephew KINSA Suture Anchor (K061154).

**E. Description of Device**

The KINSA RC Anchor is a suture anchor manufactured from PEEK polymer. The design incorporates a suture knot within the anchor body and a suture loop with a tension suture extending from the top of the anchor. This design allows the surgeon to implant the anchor, pass the suture loop through the tissue and using the tensioning suture, complete the repair without the need for knot tying.

**F. Intended Use**

The Smith & Nephew KINSA RC Suture Anchor is intended for use for the reattachment of soft tissue to bone for the following indications:

Deltoid Repairs  
Rotator Cuff Tear repairs  
Biceps tenodesis

**G. Comparison of Technological Characteristics**

The Smith & Nephew KINSA RC Suture Anchor is substantially equivalent in design, materials, function and intended use to the Smith & Nephew KINSA suture anchor, cleared in K061154. The proposed and the predicate devices both have the same intended use, indications for use, anchor material, suture material, knotless design.

**H. Summary Performance Data**

The performance testing conducted demonstrates substantial equivalence to the Smith & Nephew KINSA Suture Anchor, cleared in K061154. The testing also demonstrates that the differences in the new device and the predicate device do not raise any new issues of safety and efficacy.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Smith & Nephew, Inc.  
% Ms. Deana Boushell  
Regulatory Affairs Specialist  
Endoscopy Division  
150 Minuteman Road  
Andover, Massachusetts 01810

MAY 16 2007

Re: K070908  
Trade/Device Name: KINSA RC Suture Anchor  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: Class II  
Product Code: MBI  
Dated: March 29, 2007  
Received: April 2, 2007

Dear Ms. Boushell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

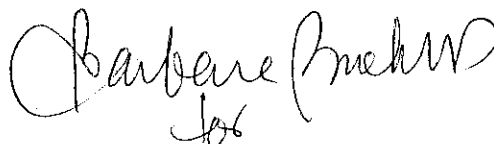
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with a large initial "M" and a small "J" or "L" at the bottom.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**510(k) Number (if known): K070908Device Name: Smith & Nephew KINSA RC Suture Anchor**Indications For Use:**

The Smith & Nephew KINSA RC Suture Anchor is intended for use for the reattachment of soft tissue to bone for the following indications:

Deltoid Repairs  
Rotator Cuff Tear repairs  
Biceps tenodesis

Prescription Use   x   AND/OR Over-The-Counter Use         
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number K070908